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Ethical Issues

Principal Investigator: FEDEROFF, HOWARD J.
Grant Number: 5U54NS045309-03
Title: Parkinson's Disease Gene Therapy Study Group

Abstract: Parkinson's disease (PD) affects about 1 million people in North America. Medications, such as levodopa, and some surgical approaches are available for PD, but offer only symptomatic therapy. New information contribute to current optimism that gene therapy might correct the molecular disturbances of PD, alleviate the symptoms of the illness and/or in retarding disease progression. Setbacks in gene therapy for other diseases underscore the importance of a purposely deliberate and careful approach that demands substantial assurances of safety and potential efficacy in advance of human testing. It is this philosophy of conservatism that will characterize the activities of our group. A coordinated stepwise progression from basic research through exhaustive preclinical evaluation prior to clinical testing is required. A multicenter, multidisciplinary collaborative group (The PD Gene Therapy Study Group [PDGTSG]) has formed and seeks support for those activities that will lead to a large-scale clinical trial of gene therapy for patients with PD. The PDGTSG consists of three different components: Cores, Principal Projects, and Pipeline Projects. Core A. Administrative Core (PI: Dr. Federoff): Houses a Steering Committee, and Vector (Chair: Dr. Lowenstein), Human Subjects/Clinical Assessment (Chair: Dr. Kurlan), Bioethics (Chair: Ms. Greenlaw), Intellectual Property (Chair: Ms. Hunter) and Biostatistics Modules (Chair: Dr. Oakes). Provides for the coordination of budgeting, committee scheduling, reports, progress preparation, and interface with NINDS staff, the clinical, scientific and lay community. Core B. Biological Measurement Core (PI: Dr. Federoff: Functions in the application shared quantitative measurements. Houses the database and the bank of vector constructs used in all studies. Project I. "Enzymatic Gene Transfer in MPTP Monkeys" (PIs: Bankiewicz and Kordower) Will comprehensively evaluate two vector platforms (rHIV and rAAV), each transducing the identical AADC gene cassette in the standardized non-human primate model. Project II. "Trophic Gene Transfer in MPTP Monkeys" (PIs: Bankiewicz and Kordower) Will comprehensively evaluate two vector platforms (rHIV and rAAV), each transducing the identical regulated GDNF gene cassette in the standardized non-human primate model. PIPELINE PROJECTS 0PPs) Focus 1: 1reproved regulation of gene expression PP I. "Tet-Regulated Vectors for Parkinson's Disease" (PI: Bohn). PP II. "Engineering RNA Switches that Respond to Dopamine and its Analogs" (PI: Breaker). Focus 2: Development of new vector platforms for application in PD disease models. PP III. "High Capacity Gutless Adenovirus" (PI: Lowenstein). PP IV. "Development of Integrating HSV

Principal Investigator: TICKLE-DEGNEN, LINDA
Grant Number: 5R01NS048059-02
Title: Culture, Gender, and Health Care Stigma in Parkinsonism

Abstract: The overall goal of the proposed research is to understand the stigmatizing role of the movement disorder of Parkinson's disease (PD) in health care practitioners' assessment of patient psychological traits, in the patient-practitioner relationship, and in the development of intervention recommendations. The first specific aim of the research is to elucidate the consequences of the operation of movement stereotypes on practitioner impressions of and conclusions about patients with PD. The second specific aim is to document the interaction of expressive masking (the diminishment of normal movement) with gender and culture on stigma outcomes. The third specific aim is to determine the degree to which practitioner expertise moderates the stigmatizing role of expressive masking on practitioner perceptions of and conclusions about patients. The fourth specific aim is to evaluate the clinical utility of the findings from the perspective of expert practitioners. Twelve Taiwanese patients (6 females and 6 males) and 12 American patients (6 females and 6 males) will be videotaped during a standardized health care interview in their respective homelands. Within each group of 6 patients (gender crossed with culture), there will be 3 patients with high expressive masking and 3 patients with normal expressive movement. Excerpts from the resulting 24 tapes will be shown to expert and novice health care practitioners in Taiwan and the U.S. who will assess patients' social and mental competence and potential for entering into a successful therapeutic relationship. In addition, the practitioners will make quality-of-life intervention recommendations. The results of the study will be presented to expert practitioners, in focus groups, who will evaluate the clinical utility of the findings and make recommendations for interventions to reduce practitioners' stigma responses. It is anticipated that PD with expressive masking will be more stigmatizing than PD without masking, especially as demonstrated in outcomes for novice compared to expert practitioners. It is also anticipated that negative outcomes of masking will be greater for female than male and American than Taiwanese patients because of different norms associated with movement expression in these groups.-

Principal Investigator: VAWTER, DOROTHY E.
Grant Number: 5R01NS040883-05
Title: ETHICAL AND POLICY CHALLENGES IN THE STUDY AND USE OF DB

Abstract: Unavailable